Appl. No.: 10/023,441
Art Unit: 1623

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of the Claims:

1-98. (canceled)

99. (new) A method of treating a disease or disorder in a mammal comprising the step of orally administering to the mammal a therapeutically effective amount of a modafinil compound:cyclodextrin mixture.

100. (new) The method of claim 99, wherein the modafinil compound:cyclodextrin mixture comprises an inclusion complex of a modafinil compound and a cyclodextrin.

101. (new) The method of claim 99, wherein the modafinil compound is modafinil.

102. (new) The method of claim 101, wherein the modafinil compound is the levorotatory form of modafinil.

103. (new) The method of claim 99, wherein the cyclodextrin is selected from the group consisting of α-cyclodextrin, β-cyclodextrin, γ-cyclodextrin, dimethyl-β-cyclodextrin, trimethyl-β-cyclodextrin, 2-hydroxymethyl-β-cyclodextrin, 2-hydroxypropyl-β-cyclodextrin, 3-hydroxypropyl-β-cyclodextrin, β-cyclodextrin sulfate, β-cyclodextrin sulfonate, β-cyclodextrin sulfobutyl ether, and mixtures thereof.

104. (new) The method of claim 99, wherein the cyclodextrin is a β-cyclodextrin.

105. (new) The method of claim 104, wherein the cyclodextrin is selected from the group consisting of β-cyclodextrin, a hydroxypropyl-β-cyclodextrin and β-cyclodextrin sulfobutyl ether.

106. (new) The method of claim 105, wherein the cyclodextrin is 2-hydroxypropyl-β-cyclodextrin.

107. (new) The method of claim 99, wherein the modafinil compound is modafinil and the cyclodextrin is 2-hydroxypropyl-β-cyclodextrin.

108. (new) The method of claim 107, wherein the modafinil compound is the levorotatory form of modafinil.

109. (new) The method of claim 99, wherein the modafinil compound:cyclodextrin mixture is in a solution form.

110. (new) The method of claim 99, wherein the modafinil compound:cyclodextrin mixture is in a solid form.

111. (new) The method of claim 99, wherein the modafinil compound:cyclodextrin mixture comprises a modafinil compound having an aqueous solubility of at least about 30 mg/ml.

112. (new) The method of claim 99, wherein the modafinil compound:cyclodextrin mixture contains cyclodextrin and a modafinil compound at a molar ratio of about 0.8:1 to 10:1.

113. (new) The method of claim 99, wherein the modafinil compound:cyclodextrin mixture contains cyclodextrin and a modafinil compound at a molar ratio of about 1:1 to about 3:1.

114. (new) The method of claim 99, wherein the modafinil compound:cyclodextrin mixture contains cyclodextrin and a modafinil compound at a molar ratio of about 1:1.

115. (new) The method of claim 99, wherein the modafinil compound is modafinil, the cyclodextrin is 2-hydroxypropyl-β-cyclodextrin, and the modafinil compound:cyclodextrin mixture contains 2-hydroxypropyl-β-cyclodextrin and modafinil at a molar ratio of about 1:1.

116. (new) The method of claim 115, wherein the modafinil compound is the levorotatory form of modafinil.

117. (new) The method of claim 99, wherein the modafinil compound:cyclodextrin mixture is orally administered to treat sleepiness, to promote wakefulness, to stimulate appetite, or to stimulate weight gain.

118. (new) The method of claim 99, wherein the modafinil compound:cyclodextrin mixture comprises at least one unit dose of a modafinil compound.

119. (new) The method of claim 118, wherein the unit dose is from about 10 mg to about 400 mg.

120. (new) The method of claim 118, wherein the unit dose is 100 mg or 200 mg.

121. (new) The method of claim 99, wherein oral administration of the modafinil compound:cyclodextrin mixture provides at least a 10% increase in the blood serum level of a modafinil compound relative to the same amount of a modafinil compound in a solid oral dosage form.

122. (new) The method of claim 99, wherein oral administration of the modafinil compound:cyclodextrin mixture provides at least a 25% increase in the blood serum level of a modafinil compound relative to the same amount of a modafinil compound in a solid oral dosage form.

123. (new) The method of claim 99, wherein oral administration of the modafinil compound:cyclodextrin mixture provides at least a 50% increase in the blood serum level of a modafinil compound relative to the same amount of a modafinil compound in a solid oral dosage form.

124. (new) The method of claims 121, 122, or 123 wherein the increase in the blood

serum level is within the first hour of oral administration to the mammal.

125. (new) The method of claim 99, wherein oral administration of the modafinil compound:cyclodextrin mixture provides substantially the blood serum profile of FIG. 1.

126. (new) A method of delivering modafinil to the bloodstream of a mammal comprising the step of orally administering to the mammal a therapeutically effective amount of a modafinil compound:cyclodextrin mixture.

127. (new) The method of claim 126, wherein the modafinil compound is modafinil.

128. (new) The method of claim 127, wherein the modafinil compound is the levorotatory form of modafinil.

129. (new) The method of claim 126, wherein the cyclodextrin is selected from the group consisting of β-cyclodextrin, a hydroxypropyl-β-cyclodextrin and β-cyclodextrin sulfobutyl ether.

130. (new) The method of claim 126, wherein the modafinil compound:cyclodextrin mixture comprises a modafinil compound having an aqueous solubility of at least about 30 mg/ml.

131. (new) The method of claim 126, wherein the modafinil compound:cyclodextrin mixture contains cyclodextrin and a modafinil compound at a molar ratio of about 1:1.

132. (new) The method of claim 126, wherein the modafinil compound:cyclodextrin mixture comprises at least one unit dose of a modafinil compound.

133. (new) The method of claim 132, wherein the unit dose is 100 mg or 200 mg.

134. (new) The method of claim 126, wherein oral administration of the modafinil compound:cyclodextrin mixture provides at least a 10% increase in the blood serum

level of a modafinil compound relative to the same amount of a modafinil compound in a solid oral dosage form.